



DEPARTMENT OF TRANSPORTATION

[4910-EX-P]

Federal Motor Carrier Safety Administration

[FMCSA-2012-0102]

Proposed Recommendations on Obstructive Sleep Apnea

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice; request for public comments.

SUMMARY: FMCSA announces proposed recommendations from the Motor Carrier Safety Advisory Committee (MCSAC) and the Medical Review Board (MRB) on Obstructive Sleep Apnea (OSA) and the medical certification of commercial motor vehicle (CMV) drivers. The MCSAC and the MRB are FMCSA advisory committees and operate in accordance with the Federal Advisory Committee Act (FACA). At the Agency's request, the committees deliberated and provided their finalized recommendations to FMCSA on February 6, 2012. The Agency proposes to adopt the recommendations as regulatory guidance after reviewing and evaluating comments received from the public.

DATES: Comments must be received on or before [Insert date 30 days after date of publication in the FEDERAL REGISTER].

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA 2012-0102 using any of the following methods:

- Federal eRulemaking Portal: Go to <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- Mail: Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, S.E., West Building Ground Floor, Room W12-140, Washington, DC 20590-0001.

- Hand Delivery: West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, S.E., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- Fax: 1-202-493-2251.

Instructions: Each submission must include the Agency name and the docket numbers for this notice. Note that all comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. Please see the Privacy Act heading below for further information.

Docket: For access to the docket to read background documents or comments, go to <http://www.regulations.gov> at any time or Room W12-140 on the ground level of the West Building, 1200 New Jersey Avenue, S.E., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the FDMS published in the Federal Register on January 17, 2008 (73 FR 3316), or you may visit <http://edocket.access.gpo.gov/2008/pdf/E8-785.pdf>.

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Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

49 CFR Section 391.41(b)(5) provides that a person is qualified physically to drive a CMV if that person has no established medical history or clinical diagnosis of a respiratory dysfunction likely to interfere with the ability to control and drive a CMV safely.

The Instructions to The Medical Examiner on the Medical Examination Report, (49 CFR 391.43), identify OSA as one of several respiratory dysfunctions that may be detrimental to safe driving as this condition may interfere with driver alertness and may cause gradual or sudden incapacitation.

FMCSA directed its two advisory committees, the MCSAC and the MRB, meet jointly and publically to deliberate on the topic of OSA and whether CMV drivers with OSA should be medically certified.

FMCSA tasked the MCSAC and the MRB with jointly providing information, concepts, and ideas the Agency should consider in developing regulatory guidance for motor carriers, CMV drivers, and medical examiners on OSA and whether drivers with this condition should be medically certified to operate CMVs in interstate commerce. FMCSA instructed the MCSAC and MRB to provide information about how to address drivers with OSA in the short-term until the Agency can consider strategies for a long-term regulatory action.

As part of the committees' process for developing recommendations to be considered for

regulatory guidance on OSA, the November 2007 Evidence Report was updated in November 2011 and presented at the December 2011 joint meeting of the MCSAC and the MRB.

After the December 2011 joint MCSAC-MRB meeting, a MCSAC-MRB subcommittee was formed in accordance with FACA requirements. The subcommittee's task was to bring recommendations back to the full joint committee for deliberation. The subcommittee met publicly on January 4 - 5, 2012, to discuss this task and prepared recommendations for the full MCSAC's and MRB's consideration and deliberation at the February 2012 joint MCSAC-MRB meeting. In February 2012 the joint committee deliberated and finalized its recommendations on OSA and medical certification of CMV drivers.

Basis for Proposed Guidance on OSA

The existing advisory criteria for the Respiratory Dysfunction requirement [391.41(b)(5)] states that "There are many conditions that interfere with oxygen exchange and may result in incapacitation, including [among others] sleep apnea. If the medical examiner detects a respiratory dysfunction, that in any way is likely to interfere with the driver's ability to safely control and drive a commercial motor vehicle, the driver must be referred to a specialist for further evaluation and therapy."

Currently, FMCSA relies on medical examiners to apply professional judgment in applying FMCSA's advisory criteria on OSA to determine whether a driver has a respiratory dysfunction such as OSA that may affect his or her ability to operate a CMV safely. The motor carrier community and medical examiners have requested that FMCSA improve the existing advisory criteria and provide more uniform regulatory guidance on OSA to the motor carrier industry and medical examiners.

The Proposed Recommendations

Introduction

The MCSAC and MRB developed and discussed several key questions in considering Task 11-05 to provide information, concepts, and ideas FMCSA should consider in developing regulatory guidance for motor carriers, CMV drivers, and medical examiners on OSA and whether drivers with this condition should be medically certified to operate CMVs in interstate commerce. These questions are listed below.

- Are individuals with OSA at an increased risk for a motor vehicle crash when compared to comparable individuals who do not have OSA?
- What disease-related factors are associated with an increased motor vehicle crash risk among individuals with OSA?
- Are individuals with OSA unaware of the presence of the factors that appear to be associated with an increased motor vehicle crash risk?
- Are there screening/diagnostic tests available that will enable examiners to identify those individuals with OSA who are at an increased risk for a motor vehicle crash?
- Which treatments have been shown to effectively reduce crash risk among individuals with OSA?
- What is the length of time required following initiation of an effective treatment for individuals with OSA to reach a degree of improvement that would permit safe driving?
- How soon following cessation of treatment will individuals with OSA demonstrate reduced driver safety (i.e., as a consequence of non-compliance)?

Discussion of the above questions formed the basis of the joint MCSAC-MRB recommendations for consideration by FMCSA when developing regulatory guidance regarding OSA. The joint

MCSAC-MRB recommendations are summarized below.

I. General Recommendations Regarding OSA

- A. OSA diagnosis precludes unconditional certification.
- B. A driver with an OSA diagnosis may be certified if the following conditions are met:
 - 1. The driver has untreated OSA with an apnea-hypopnea index (AHI) of less than or equal to 20 (i.e., mild-to-moderate OSA), and
 - 2. The driver does not admit to experiencing excess sleepiness during the major wake period, or
 - 3. The driver's OSA is being effectively treated.
- C. Notes on AHI threshold:
 - 1. The AHI threshold is used to prioritize drivers with OSA who need immediate treatment.
 - 2. The AHI threshold is set at 20 because crash risk in the moderate-to-severe OSA range is statistically higher than for drivers with mild OSA.
 - 3. Although an AHI of 15 is likely a safer threshold, there is no data to support this and such a threshold may be less practical in terms of enrolling patients for treatment.
 - 4. Drivers with mild OSA (AHI levels as low as 5) may benefit from OSA treatment, and should be encouraged to explore treatment options.

5. Drivers with an AHI between 5 and 20 should be encouraged to seek treatment if they have a history involving a fatigue-related crash or a DOT-defined single vehicle crash,¹ or if they report sleepiness while operating a motor vehicle.
- D. A driver with an OSA diagnosis may be recertified annually, based on demonstrating compliance with treatment.
1. Minimally acceptable compliance with Positive Airway Pressure (PAP) treatment consists of at least 4 hours per day of use on 70 percent of days.
 2. Drivers should be made aware that more hours of PAP use is preferable and that optimal treatment efficacy occurs with 7 or more hours of daily use during sleep.

II. Immediate Disqualification or Certification Denial

- A. Drivers should be disqualified immediately or denied certification if any of the following conditions are met:
1. The driver admits to experiencing excessive sleepiness during the major wake period while driving; or
 2. The driver experienced a crash associated with falling asleep; or
 3. The driver has been found non-compliant with treatment per Recommendation I. D.

III. Conditional Certification

- A. Drivers may be granted conditional certification if any of the following conditions are met:

¹ Per 49 CFR 390.5, “accident” means (1) an occurrence involving a commercial motor vehicle operating on a highway in interstate or intrastate commerce which results in: (i) A fatality; (ii) Bodily injury to a person who, as a result of the injury, immediately receives medical treatment away from the scene of the accident; or (iii) One or more motor vehicles incurring disabling damage as a result of the accident, requiring the motor vehicle(s) to be transported away from the scene by a tow truck or other motor vehicle.

1. The driver has an AHI of greater than 20 until compliant with PAP; or
2. The driver has undergone surgery and is pending post-op findings per Recommendations VI – VIII; or
3. The driver has a Body Mass Index (BMI) of greater than or equal to 35 kg/m² pending a sleep study.

B. Notes on BMI threshold:

1. The MRB is in agreement that a BMI threshold of 33 is supported by studies.
2. MCSAC member Robert Petrancosta (Con-Way Freight) asserted that a BMI threshold should be objectively related to crash risk.

C. Conditional certification should include the following elements:

1. A driver with a BMI of greater than or equal to 35 kg/m² may be certified for 60 days pending sleep study and treatment (if the driver is diagnosed with OSA).
2. Within 60 days, if a driver being treated with OSA is compliant with treatment (per Recommendations I.D. and V – IX), the driver may receive an additional 90-day conditional certification.
3. After 90 days, if the driver is still compliant with treatment, the driver may be certified for no more than 1 year. Future certification should be dependent on continued compliance.

D. OSA Screening (i.e., identifying individuals with undiagnosed OSA)

1. In addition to a BMI of 35 or above, the following information may help a clinician diagnose OSA:
 - a. Symptoms of OSA may include loud snoring, witnessed apneas, or sleepiness during the major wake period;

b. Risk factors of OSA may include the following factors. However, a single risk factor alone may not infer risk, and a combination of multiple factors should be examined.

i. Factors associated with high risk:

- Small or recessed jaw
- Small airway (Mallampati Scale score of Class 3 or 4)
- Neck size ≥ 17 inches (male), 15.5 inches (female)
- Hypertension (treated or untreated)
- Type 2 diabetes (treated or untreated)
- Hypothyroidism (untreated)

ii. Other factors:

- BMI greater than or equal to 28 kg/m^2
- Age 42 and above
- Family history
- Male or post-menopausal female
- Experienced a single-vehicle crash

IV. Method of Diagnosis and Severity

A. Methods of diagnosis include in-laboratory polysomnography, at-home polysomnography, or an FDA-approved limited channel ambulatory testing device which ensures chain of custody.

1. In-laboratory polysomnography, which is more comprehensive, should be considered when the clinician suspects another sleep disorder in addition to sleep apnea.

2. New OSA screening technologies will likely emerge.
- B. The driver should be tested while on usual chronic medications.
- C. The MCSAC and MRB did not consider AHI levels from unattended (i.e., in-home) studies, only in-laboratory sleep studies that detect the arousal component of hypopneas, as well as saturation.
1. An in-home sleep study may underestimate AHI when compared to an in-laboratory sleep study because the in-home study likely does not consider total sleep time.
 2. The medical examiner should use clinical judgment when interpreting the results of an unattended sleep study.
 - a. If the clinician believes the level of apnea is greater than the level reported by the in-home study, the clinician should consider recommending an in-laboratory sleep study.

V. Treatment: Positive Airway Pressure (PAP)

- A. All individuals with OSA should be referred to a clinician with relevant expertise.
- B. PAP is the preferred OSA therapy.
- C. Adequate PAP pressure should be established through one of the following methods:
1. Titration study with polysomnography
- D. Auto-titration system

A driver who has been disqualified may be conditionally certified (per Recommendation III) if the following conditions are met:

1. The driver is successfully treated for one week; and

2. The driver can demonstrate at least minimal compliance (i.e., 4 hours per use on 70 percent of nights); and
3. The driver does not report excessive sleepiness during the major wake period.

VI. Treatment: Bariatric surgery

- A. After bariatric surgery, a driver may be certified if the following conditions are met:
 1. Six months have passed since the surgery (for weight loss); and
 2. The driver has been compliant with PAP for six months; and
 3. The driver has been cleared by the treating physician; and
 4. The driver does not report excessive sleepiness during the major wake period.
- B. After six months have passed since surgery, if the apnea appears to have resolved a repeat sleep study should be considered to test for the presence of ongoing sleep apnea.
- C. Annual recertification
 1. If clinically indicated, repeat the sleep study.

VII. Treatment: Oropharyngeal surgery, Facial bone surgery

- A. After oropharyngeal or facial bone surgery, a driver may be certified if the following conditions are met:
 1. One month has passed since surgery; and
 2. The driver has been cleared by the treating physician; and
 3. The driver does not report excessive sleepiness during the major wake period.
- B. After one month has passed since surgery, if the apnea appears to have resolved a repeat sleep study should be considered to test for the presence of ongoing sleep apnea.
- C. Annual recertification
 1. If clinically indicated, repeat the sleep study.

VIII. Treatment: Tracheostomy

- A. After a tracheostomy, a driver may be certified if the following conditions are met:
 - 1. One month has passed since surgery; and
 - 2. The driver has been cleared by the treating physician; and
 - 3. The driver does not report excessive sleepiness during the major wake period.
- B. After one month has passed since surgery, if the apnea appears to have resolved a repeat sleep study should be considered to test for the presence of ongoing sleep apnea.
- C. Annual recertification
 - 1. If clinically indicated, repeat the sleep study.

IX. Treatment Alternatives

- A. There is limited data regarding compliance and long-term efficacy of dental appliances and these technologies are not approved alternatives at this time.²
- B. Surgical treatment is acceptable (See Recommendations VI – VIII).

Request for Comments

FMCSA requests comments on the above joint recommendations provided to the Agency by its Motor Carrier Safety Advisory Committee and Medical Review Board on Obstructive Sleep Apnea. Commenters are requested to provide supporting data wherever appropriate.

² Based on public comments received at the February MCSAC meeting, one member (Danny Schnautz, Clark Freight Lines, Inc., Pasadena, TX) suggested that the efficacy of dental appliances may need to be reviewed.

The Agency will consider all comments received before the close of business [Insert date 30 days after date of publication in the FEDERAL REGISTER]. Comments will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. The Agency will file comments received after the comment closing date in the public docket, and will consider them to the extent practicable. In addition to late comments, FMCSA will also continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should monitor the public docket for new material.

Issued on: April 16, 2012

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Associate Administrator of Policy

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